

and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label.

[64 FR 56453, Oct. 20, 1999]

#### **§ 610.64 Name and address of distributor.**

The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: “Manufactured for \_\_\_\_\_”, “Distributed by \_\_\_\_\_”, “Manufactured by \_\_\_\_\_ for \_\_\_\_\_”, “Manufactured for \_\_\_\_\_ by \_\_\_\_\_”, “Distributor: \_\_\_\_\_”, or “Marketed by \_\_\_\_\_”. The qualifying phrases may be abbreviated.

[61 FR 57330, Nov. 6, 1996]

#### **§ 610.65 Products for export.**

Labels on packages or containers of products for export may be adapted to meet specific requirements of the regulations of the country to which the product is to be exported provided that in all such cases the minimum label requirements prescribed in § 610.60 are observed.

### **PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS**

#### **Subpart A—Whole Blood**

Sec.

- 640.1 Whole Blood.
- 640.2 General requirements.
- 640.3 Suitability of donor.
- 640.4 Collection of the blood.
- 640.5 Testing the blood.
- 640.6 Modifications of Whole Blood.

#### **Subpart B—Red Blood Cells**

- 640.10 Red Blood Cells.
- 640.11 General requirements.
- 640.12 Suitability of donor.
- 640.13 Collection of the blood.
- 640.14 Testing the blood.
- 640.15 Pilot samples.
- 640.16 Processing.
- 640.17 Modifications for specific products.

#### **Subpart C—Platelets**

- 640.20 Platelets.
- 640.21 Suitability of donors.
- 640.22 Collection of source material.
- 640.23 Testing the blood.
- 640.24 Processing.
- 640.25 General requirements.
- 640.27 Emergency provisions.

#### **Subpart D—Plasma**

- 640.30 Plasma.
- 640.31 Suitability of donors.
- 640.32 Collection of source material.
- 640.33 Testing the blood.
- 640.34 Processing.

#### **Subpart E [Reserved]**

#### **Subpart F—Cryoprecipitate**

- 640.50 Cryoprecipitate AHF.
- 640.51 Suitability of donors.
- 640.52 Collection of source material.
- 640.53 Testing the blood.
- 640.54 Processing.
- 640.55 U.S. Standard preparation.
- 640.56 Quality control test for potency.

#### **Subpart G—Source Plasma**

- 640.60 Source Plasma.
- 640.61 Informed consent.
- 640.62 Medical supervision.
- 640.63 Suitability of donor.
- 640.64 Collection of blood for Source Plasma.
- 640.65 Plasmapheresis.
- 640.66 Immunization of donors.
- 640.67 Laboratory tests.
- 640.68 Processing.
- 640.69 General requirements.
- 640.70 Labeling.
- 640.71 Manufacturing responsibility.
- 640.72 Records.
- 640.73 Reporting of fatal donor reactions.
- 640.74 Modification of Source Plasma.
- 640.76 Products stored or shipped at unacceptable temperatures.

#### **Subpart H—Albumin (Human)**

- 640.80 Albumin (Human).
- 640.81 Processing.
- 640.82 Tests on final product.
- 640.83 General requirements.
- 640.84 Labeling.

#### **Subpart I—Plasma Protein Fraction (Human)**

- 640.90 Plasma Protein Fraction (Human).
- 640.91 Processing.
- 640.92 Tests on final product.
- 640.93 General requirements.
- 640.94 Labeling.